AO 120 (Rev. 2/99)

TO: Mail Stop 8 Director of the U.S. Patent & Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK

In Compliance with 35 § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the U.S. District Court No. District of CA on the following X Patents or ☐ Trademarks:

DOCKET NO.	DATE FILED	U.S. DISTRICT COURT
CV 10-01111 VRW	3-15-10	450 Golden Gate Ave., Box 36060, San Francisco, CA 94102

PLAINTIFF	DEFENDANT
CAREFUSION CORPORATION, ET AL.	MEDTRONIC, INC., ET AL.

	PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1	6,235,043		SEE ATTACHED COMPLAINT
2	6,241,734		
3	6,248,110		
4	6,613,054		
5			

In the above—entitled case, the following patent(s) have been included:

DATE INCLUDED	INCLUDED BY ☐ Amendment ☐ Answer ☐ Cross Bill ☐ Other Pleading	
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1		
2		
3		
4		
5		

In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT

CLERK	(BY) DEPUTY CLERK	DATE
Richard W. Wieking	Felicia Reloba	March 23, 2010

Copy 1—Upon initiation of action, mail this copy to Commissioner **Copy 3—Upon termination of action, mail this copy to Commissioner**
Copy 2—Upon filing document adding patent(s), mail this copy to Commissioner **Copy 4—Case file copy**

58. On July 12, 2004, Kyphon amended its complaint against Disc-O-Tech in the District of Delaware action to include allegations that Disc-O-Tech infringed the '734 and '054 patents.

59. Specifically, Kyphon alleged that Disc-O-Tech's SKy Bone Expander – a non-balloon product used to treat vertebral compression fractures by creating a void in the vertebral body prior to cement injection – infringed the above-referenced patents.

60. Kyphon and Disc-O-Tech ultimately settled their lawsuits.

61. Subsequently, on December 20, 2006, as part of Defendants' anticompetitive scheme, Kyphon acquired the assets and intellectual property of Disc-O-Tech. Kyphon's acquisition of Disc-O-Tech's assets and intellectual property furthered Defendants' scheme to eliminate and/or diminish competition in the minimally invasive vertebral compression fracture treatment product market and in the alternative kyphoplasty product market.

62. On October 5, 2007, the Federal Trade Commission filed a complaint against Kyphon's acquisition of Disc-O-Tech. (*See* Ex. L, Federal Trade Commission Complaint.)

63. Ultimately, the Federal Trade Commission required Kyphon (which was then being acquired by Medtronic) to divest Disc-O-Tech's Confidence line of products relating to bone cement injection, but allowed Kyphon to keep, among other things, Disc-O-Tech's SKy Bone Expander product line. (*See* Ex. M, Federal Trade Commission Decision.)

64. On information and belief, Defendants have never marketed or sold the SKy Bone Expander.

65. Defendants' acquisition of Disc-O-Tech, therefore, had the effect of eliminating and/or diminishing competition in the minimally invasive vertebral compression fracture treatment product market and in the alternative kyphoplasty product market by preventing a competitive product from entering those markets, by eliminating a competitor from those markets, and further adding to their scheme of enforcing and threatening to enforce their patents, including invalid and unenforceable patents.

66. On November 23, 2005, Kyphon, along with Dr. Sandhu, filed a lawsuit against several Medtronic entities, *i.e.*, Medtronic's subsidiaries. Kyphon and Dr. Sandhu alleged, *inter alia*, that Medtronic's subsidiaries stole Dr. Sandhu's trade secrets relating to the treatment of vertebral

compression fractures and, in violation of the patent laws, filed patent applications relating to Dr. Sandhu's trade secrets without naming Dr. Sandhu as an inventor. (*See Sandhu and Kyphon Inc. v. Medtronic Sofamor Danek, Inc., et al.*, Civil Action No. 05-2863 (W.D. Tenn.).)

67. On information and belief, the patent rights Kyphon alleged that Medtronic obtained embodying Dr. Sandhu's devices for the treatment of vertebral compression fractures include at least U.S. Patent Nos. 6,676,665.

68. On information and belief, Kyphon also alleged that Medtronic violated the patent laws by filing at least two additional applications embodying Dr. Sandhu's devices for the treatment of vertebral compression fractures, namely U.S. Patent Application Serial No. 10/756,970 and U.S. Patent Application Serial No. 10/778,650 (now issued as United States Patent No. 7,641,664).

69. On April 26, 2006, Kyphon and Dr. Sandhu amended their complaint against Medtronic's subsidiaries to add allegations of infringement of the '888 patent, the '404 patent, the '043 patent, United States Patent No. 6,440,138, and United States Patent No. 6,863,672. (*See Sandhu and Kyphon, Inc. v. Medtronic Soframor Danek, Inc., et al.*, Civil Action No. 05-2863 (W.D. Tenn).)

70. During its litigation with Kyphon, Medtronic, through its subsidiaries, repeatedly admitted and alleged that the patents asserted by Kyphon were invalid.

71. For example, on August 3, 2006, Medtronic, through its subsidiaries, answered Kyphon's Amended Complaint and stated the following:

> **Twenty-Second Defense**
>
> **(Invalidity of Kyphon's Patents)**
>
> The Kyphon patents asserted against Medtronic, namely the '888, '404, '043, '138, and '672 patents are invalid because they fail to satisfy the requirements of 35 U.S.C. § 101, et seq., including, without limitation, sections 101, 102, 103, and 112.

(Ex. N, Medtronic Answer to Amended Complaint at 18.)

72. On April 12, 2007, Medtronic, through its subsidiaries, filed an Amended Answer to the Amended Complaint and again twice stated that the patents asserted by Kyphon were invalid:

Twenty-Second Defense

(Invalidity of Kyphon's Patents)

The Kyphon patents asserted against Medtronic, namely the '888, '404, '043, '138, and '672 patents are invalid because they fail to satisfy the requirements of 35 U.S.C. § 101, et seq., including, without limitation, sections 101, 102, 103, and 112.

84. The claims of Kyphon's '888, '404, '138, '672, and '043 patents are invalid for failure to comply with one or more provisions of the Patent Laws of the United States, Title 35, United States Code, §§ 101 et seq., including without limitation Sections 101, 102, 103 and/or 112.

(Ex. I, Medtronic Amended Answer to Amended Complaint at 20 and 37.)

73. In its April 12, 2007 Amended Answer to the Amended Complaint, Medtronic, through its subsidiaries, also included detailed allegations regarding its belief that the '888 and '404 patents were unenforceable due to inequitable conduct. (*See id.* at ¶¶ 67-77.)

74. In particular, Medtronic, through its subsidiaries, alleged and admitted that though the applicants were aware that vertebroplasty had been used in the prior art to treat vertebral compression fractures, the applicants intentionally misrepresented to the United States Patent and Trademark Office that the only known treatment for vertebral compression fractures was bed rest and aspirin:

Seventh Counterclaim by MSD Inc., MSD USA, and SDGI

(Declaratory Judgment of Unenforceability Due to Inequitable Conduct)

67. MSD Inc., MSD USA, and SDGI reassert and incorporate by reference the allegations set forth in paragraphs 1-66 as though fully set forth herein.

68. This Counterclaim is an action for declaratory judgment pursuant to 28 U.S.C. §§ 2201 et seq.

69. Kyphon filed suit against Medtronic and alleged in its Complaint that MSD Inc., MSD USA, and SDGI infringe United States Patent Nos. 4,969,888 ("the '888 patent"), 5,108,404 ("the '404 patent"), 6,235,043 ("the '043 patent"), 6,440,138 ("the '138 patent") and 6,863,672 ("the '672 patent"). MSD Inc., MSD USA, and SDGI now seek a declaration of unenforceability due to inequitable conduct as to the '888, '404, and '138 patents, and any applications or patents related thereto.

United States Patent Application Serial No. 07/308,724 (the "'724 application")

70. The '724 application was filed on February 9, 1989. The '724 application was pending at the United States Patent and Trademark Office (the "PTO") until its issuance, as the '888 patent, on November 13, 1990. The named inventors on the '724 application are Arie Scholten and Mark A. Reiley, and the prosecuting attorneys were the law firm of Townsend and Townsend. During the entirety of the time that the '724 application was pending before the PTO, all those substantively involved with the prosecution of the '724 application had a duty to disclose to the PTO information material to the patentability of one or more claims of the application.

71. In the background section of the '724 application, the applicants stated that the only methods of treatment for vertebral compression fractures were bed rest and aspirin:

> Osteoporotic vertebral body compression fractures are currently treated with bed rest, analgesics, and intravenous hydration during the first week after onset of the problem. These steps are followed by the prescription of a soft or firm spinal corset, depending upon the physician's preference. In most cases, the corset is not worn because the patient suffers much discomfort and oftentimes greater discomfort than that due to the fracture of the vertebral body. The fracture pain lasts from two to eight months. In many cases, patients with osteoporotic vertebral body collapse fractures require about one week in an acute care hospital and two to three weeks in an extended care facility until they are able to move about independently and with only moderate pain. Current treatment does not substantially alter the conditions of the vertebral body.

See Prosecution History for the '724 Application filed on February 9, 1989 at Pg. 1, line 23 – Pg. 2, line 4. The applicants made this representation to the PTO despite having specific knowledge of other, more advanced medical procedures for the treatment of vertebral compression fractures.

72. Specifically, the applicants were aware, prior to filing the '724 application that a medical procedure known as vertebroplasty was being performed as a method of treatment of vertebral fractures. Vertebroplasty is a percutaneous procedure for fixation of vertebral fractures by the introduction of a bone filler, such as bone cement, by use of a needle. This procedure reads on elements of one or more of the claims of the '724 application.

73. One or more of the inventors, and/or others substantively involved with the filing and prosecution of the '724 application, failed to disclose the inventors' knowledge of vertebroplasty to the PTO for consideration in the '724 patent application. Moreover, the inventors and/or others substantively involved with the filing and prosecution of the '724 application intentionally misrepresented the state of the prior art to the PTO. Vertebroplasty is material prior art to the claims of the '724 patent. In doing the aforesaid acts, one or more of the inventors, and/or others substantively involved with the filing and prosecution of the '724 application, violated the duty of disclosure and duty of candor, and did so with the intent to deceive the PTO as evidenced by the fact that those with a duty to disclose knew of the existence of this highly material art, yet failed to disclose it to the PTO and intentionally misrepresented the state of the art. This misrepresentation and failure to disclose material art renders the claims of the '888 patent, and all patents and patent applications related to the '724 application, unenforceable.

United States Patent Application Serial No. 07/567,862 (the "'862 application")

74. The '862 application was filed on August 15, 1990. The '862 application was pending at the PTO until its issuance, as the '404 patent, on April 28, 1992. The named inventors on the '862 application are Arie Scholten and Mark A. Reiley, and the prosecuting attorneys were the law firm of Townsend and Townsend. During the entirety of the time that the '862 application was pending before the PTO, all those substantively involved with the prosecution of the '862 application had a duty to disclose to the PTO information material to the patentability of one or more claims of the application.

75. In the background section of the '862 application, the applicants stated that the only methods of treatment for vertebral compression fractures were bed rest and aspirin:

> Osteoporotic vertebral body compression fractures are currently treated with bed rest, analgesics, and intravenous hydration during the first week after onset of the problem. These steps are followed by the prescription of a soft or firm spinal corset, depending upon the physician's preference. In most cases, the corset is not worn because the patient suffers much discomfort and oftentimes greater discomfort than that due to the fracture of the vertebral body. The fracture pain lasts from two to eight months. In many cases, patients with osteoporotic vertebral body collapse fractures require about one week in an acute care hospital and two to three weeks in an extended care facility until they are able to move about independently and with only moderate pain. Current treatment does not substantially alter the conditions of the vertebral body.

See Prosecution History for the '862 Application filed on August 15, 1990, at Pg. 1, line 29 – Pg. 2, line 9. The applicants made this representation to the PTO despite having specific knowledge of other, more advanced medical procedures for the treatment of vertebral compression fractures.

76. Specifically, the applicants were aware, prior to filing the '862 application that a medical procedure known as vertebroplasty was being performed as a method of treatment of vertebral fractures. Vertebroplasty is a procedure fixing vertebral fractures by the introduction of a bone filler such as bone cement. The procedure reads on elements of one or more of the claims

77. One or more of the inventors, and/or others substantively involved with the filing and prosecution of the '862 application failed to disclose the inventors' knowledge of vertebroplasty to the PTO for consideration in the '862 patent application. Moreover, the inventors and/or others substantively involved with the filing and prosecution of the '862 application intentionally misrepresented the state of the prior art to the PTO. In doing the aforesaid acts, one or more of the inventors, and/or others substantively involved with the filing and prosecution of the '862 application violated the duty of disclosure and duty of candor, and did so with the intent to deceive the PTO as evidenced by the fact that those with a duty to disclose knew of the existence of this highly material art, yet failed to disclose it to the PTO and intentionally misrepresented the state of the art. This misrepresentation and failure to disclose material art renders the claims of the '404 patent, and all patents and patent applications related to the '862 application, unenforceable.

(*Id.*)

75. In an addition to its answer and counterclaims alleging the invalidity and unenforceability of at least the '888 and '404 patents, on October 17, 2006, Medtronic, through its subsidiaries, also filed summary judgment motions asserting that certain claims of the '404 patent were invalid under 35 U.S.C. §§ 102 and 112. (*See* Exs. O and P, Medtronic's Oct. 17, 2006 Motions For Summary Judgment.)

76. On October 28, 2006, Medtronic, through its subsidiaries, filed yet another summary judgment motion again asserting that certain claims of the '404 patent were invalid under 35 U.S.C. § 102 in light of an additional prior art reference. (*See* Ex. Q, Medtronic's Oct. 28, 2006 Motion For Summary Judgment.)

77. Before the district court in the above-referenced litigation could issue a final ruling on the merits of Medtronic's invalidity and unenforceability claims, Medtronic acquired Kyphon for approximately $4 billion. (Exs. R and S, Medtronic July 27, 2007 and Nov. 2, 2007 Press Releases.) This announced acquisition occurred approximately only three months after Medtronic, through its subsidiaries, had expressly asserted that Kyphon's basic patents, namely the '888 and '404 patents, had been procured through inequitable conduct and were unenforceable.

78. Prior to Medtronic's acquisition of Kyphon, the investment community recognized that Medtronic would have been a strong competitor to Kyphon in the minimally invasive vertebral compression fracture treatment product market and in the alternative kyphoplasty product market. (Ex. T, "Why Kyphon Faces Intensifying Competitor," Aug. 12, 2004; Ex. U, "Kyphon shares tumble on downgrade," June 1, 2006.)

79. On information and belief, after acquiring Kyphon, Medtronic stopped marketing its vertebroplasty and kyphoplasty products, namely its ACRUATE™ and ARCUATE™ XP products, thus eliminating yet another competitive line of products.

80. On information and belief, Medtronic's acquisition of Kyphon, eliminated the potential for imminent significant competition in the minimally invasive vertebral compression

fracture treatment product market and in the alternative kyphoplasty product market in furtherance of Defendants' scheme to eliminate competition in those markets.

Defendants' Continuation Of Kyphon's Anticompetitive Acquisition Scheme

81. Defendants continued Kyphon's scheme of acquiring patents and other assets from third parties in the minimally invasive vertebral compression fracture treatment product market and in the alternative kyphoplasty market in furtherance of Defendants' scheme to eliminate competition in those markets.

82. For example, on November 17, 2008 Medtronic announced that it had acquired the assets and intellectual property of Pabban Development, Inc. (Ex. V, Medtronic Nov. 17, 2008 Press Release at 1.)

83. On information and belief, the intellectual property acquired included at least the United States Patent Application Publication 20050180806.

84. Medtronic stated in its press release that it intends to use the bone cement delivery system it acquired from Pabban with its kyphoplasty products. (*Id.*)

85. On information and belief, Medtronic's acquisition of Pabban, including Pabban's intellectual property, was part of the Defendants' scheme and had the effect of eliminating and/or diminishing competition in the minimally invasive vertebral compression fracture treatment product market and in the alternative kyphoplasty product market because it eliminated a potential competitor from those markets.

Defendants' Anticompetitive Use Of Patent Rights It Knew To Be Invalid And/Or Unenforceable

86. After acquiring Kyphon's patents, including patents that they knew to be invalid and/or enforceable, Defendants embarked on multiple public threats to enforce their patent rights.

87. For example, on July 2, 2006, Medtronic publicly stated that "Medtronic will go to court if necessary to enforce its patents." (Ex. W, Steve Hart, "Patent Protection: High-Tech Companies Battle To Defend Trade Secrets Key To Their Financial Success," Press Democrat, July 2, 2006.)

88. On information and belief, Defendants' patent enforcement policy was publicized and well-known to any potential or current competitor.

89. Despite Defendants' well-known policy of patent enforcement and Kyphon's well-known policy of enforcing its patents in the minimally invasive vertebral compression fracture treatment product market and in the alternative kyphoplasty product market, after acquiring from Kyphon patent rights they knew to be invalid and/or unenforceable, Defendants failed to seek reexamination of, disclaim and/or dedicate to the public the acquired patents that they knew to be invalid and unenforceable. Specifically, though Medtronic, through its subsidiaries, repeatedly asserted during its prior litigation with Kyphon that, among others, the patents that covered the basic kyphoplasty procedure – namely, the '888 and '404 patents – were both invalid and unenforceable, Defendants never disclaimed or dedicated these patents to the public.

90. Instead, as part of their anticompetitive, predatory, exclusionary, and/or inequitable scheme, Defendants continued to issue statements touting their robust patent enforcement policy.

91. For example, on April 25, 2008 in its Form 10-K Annual Report, Medtronic publicly stated that Medtronic "rel[ies] on a combination of patents, trade secrets and nondisclosure and non-competition agreements to protect our proprietary intellectual property, and will continue to do so." Medtronic also stated that Medtronic "intend[s] to defend against any threats to our intellectual property." (Ex. X, Medtronic April 25, 2008 Annual Report filed with the SEC at 34.)

92. On May 20, 2008, in an Earnings Conference Call, Medtronic again reiterated its patent enforcement policy. Specifically, Medtronic stated that "Kyphon and Biologics helped to partially offset continued competitive pressures on our [Medtronic] spinal products in the United States. We remain committed to our strategy of raising the bar of competition....We also remain committed to enforcing our portfolio of intellectual property." (Ex. Y, Medtronic May 2008 Earnings Call at 3.)

93. In addition to these public statements threatening enforcement of its patent rights, Defendants also took specific affirmative steps to protect their interest in patents that they had obtained from third parties, including the invalid and/or unenforceable patent rights they acquired from Kyphon.

94. For example, as part of its $4 billion purchase of Kyphon, Medtronic Spine accepted assignments to third party patents, including patents they knew to be invalid and/or unenforceable

(*e.g.*, the '888 and '404 patents). Medtronic Spine then took affirmative steps to ensure its ability to fully enforce these patents against competitors in the minimally invasive vertebral compression fracture treatment product market and in the alternative kyphoplasty product market by recording its assignments to the '888 and '404 patents, among others, with the United States Patent and Trademark Office on May 9, 2008.

95. On June 9, 2008, Defendants took further affirmative steps to ensure that they could enforce these patents against competitors in the minimally invasive vertebral compression fracture treatment product market and in the alternative kyphoplasty product market by recording with the United States Patent and Trademark Office assignments from Medtronic Spine of the '888 and '404 patents, among others, to Medtronic's subsidiary Kyphon SARL.

96. Defendants' policy of enforcing its patent rights (including patents acquired from third parties) combined with their refusal to disclaim, dedicate to the public, or seek reexamination on patents they acquired yet knew to be invalid and/or unenforceable were part of the Defendants' anticompetitive, predatory, exclusionary, and/or inequitable scheme and had the effect of eliminating and/or diminishing competition in the minimally invasive vertebral compression fracture treatment product market and in the alternative kyphoplasty product market by preventing others from entering those markets.

CareFusion's Development And Imminent Product Launch Of Its Kyphoplasty Product

97. Since approximately 2001-2002, CareFusion, or its predecessors, has sold bone cement delivery systems.

98. Since approximately 2003-2004, CareFusion, or its predecessors, has sold bone cement.

99. Since approximately 2005-2006, CareFusion, or its predecessors, has sold bone cement for vertebroplasty.

100. Since approximately 2006-2007, CareFusion, or its predecessors, has sold bone cement delivery systems for vertebroplasty.

Plaintiffs CareFusion Corporation and CareFusion 2200, Corporation (collectively "CareFusion") bring this Complaint against Defendants Medtronic, Inc., Medtronic Spine LLC, and Kyphon SARL (collectively "Defendants") seeking relief for Defendants' anticompetitive, predatory, exclusionary, and/or inequitable conduct in violation of the antitrust laws of the United States, 15 U.S.C. §§ 1 et. seq. CareFusion also seeks a declaration that the claims of United States Patent No. 6,235,043 entitled "Inflatable Device For Use In Surgical Protocol Relating To Fixation Of Bone" ("the '043 patent"), United States Patent No. 6,241,734 entitled "Systems And Methods For Placing Materials Into Bone" ("the '734 patent"), United States Patent No. 6,248,110 entitled "Systems And Methods For Treating Fractured Or Diseased Bone Using Expandable Bodies" ("the '110 patent"), and United States Patent No. 6,613,054 entitled "Systems And Methods For Placing Materials Into Bone" ("the '054 patent") are invalid and/or not infringed by CareFusion. The '043, '734, '110, and '054 patents are attached hereto as Exhibits A – D, respectfully. CareFusion alleges as follows:

1. CareFusion has been the victim of a scheme by the Defendants to keep competitors out of the minimally invasive vertebral compression fracture treatment product market and in the alternative kyphoplasty product market. Defendants' scheme includes acquisition of assets from third parties in an illegal attempt to monopolize, monopolization, and obtaining and acquiring knowingly invalid and unenforceable patents and asserting or threatening to assert these invalid and unenforceable patents. Defendants have eliminated competition and obtained approximately 85% or more market share in the minimally invasive vertebral compression fracture treatment product market and approximately 97% or more market share in the alternative kyphoplasty product market. Defendants have engaged in predatory conduct to eliminate CareFusion and others as viable competitors. In doing so, Defendants have violated the antitrust laws of the United States. CareFusion brings this action for relief from the harm that Defendants' illegal scheme has caused.

THE PARTIES

2. CareFusion Corporation is a corporation organized under the laws of the State of Delaware and has a principal place of business at 3750 Torrey View Court, San Diego, California.

3. CareFusion 2200, Corporation is a corporation organized under the laws of the

101. For years CareFusion has been interested in expanding its position in the minimally invasive vertebral compression fracture treatment product market and/or entering the alternative kyphoplasty market by developing a balloon and/or other kyphoplasty product.

102. Realizing that Kyphon and Defendants had a history of enforcing and threatening competitors with the '888 and '404 patents (among other patents) (*see supra* at ¶¶ 54-68 and 85-95), CareFusion made a business decision to wait until the '888 and '404 patents expired before launching its balloon kyphoplasty product.

103. The '888 and '404 patents expired on February 9, 2009.

104. On January 28, 2009, CareFusion applied for FDA approval of its 8 gauge Inflatable Bone Tamp device for use in kyphoplasty.

105. CareFusion initial's January 28, 2009 FDA application was strategically timed so that CareFusion would receive FDA approval for its 8 gauge Inflatable Bone Tamp device after the '888 and '404 patents had expired.

106. After the '888 and '404 patents expired, on July 1, 2009, CareFusion received FDA approval for its 8 gauge Inflatable Bone Tamp device for use in kyphoplasty.

107. After the '888 and '404 patents expired, CareFusion applied for FDA approval of its 10 gauge Inflatable Bone Tamp device for use in kyphoplasty.

108. On February 23, 2010, CareFusion received FDA approval for its 10 gauge Inflatable Bone Tamp device for use in kyphoplasty.

109. On March 13-18, the Society of Interventional Radiology is hosting the 35th Annual Scientific meeting in Tampa, Florida. CareFusion's AVA*max*™ balloon kyphoplasty products will be marketed, displayed and/or demonstrated at the meeting.

110. CareFusion intends to do a full market release of its AVA*max*™ balloon kyphoplasty products on or around April 2010.

111. As of the date of this Complaint, CareFusion has manufactured, at its facilities in the United States, the AVA*max*™ balloon kyphoplasty products to support its imminent product launch currently planned for April 2010.

Defendants' Response To CareFusion's Imminent Product Launch

112. After CareFusion received FDA approval for its 8 gauge balloon kyphoplasty product and/or after it announced its intention to launch a balloon kyphoplasty line of products in or around April 2010, Defendants issued numerous threatening statements directed towards CareFusion as part of Defendants' scheme to eliminate competitors, and specifically CareFusion, in the minimally invasive vertebral compression fracture treatment product market and in the alternative kyphoplasty product market.

113. On August 25, 2009, Medtronic held an Earnings Conference Call. During that conference call, Medtronic's Chairman & CEO, Bill Hawkins, announced that "Medtronic has and will vigorously defend its intellectual property rights in all of our markets, **including balloon kyphoplasty**." (Ex. Z, Medtronic Aug. 25, 2009 Earnings Conference Call at 3 (emphasis added).)

114. On information and belief, these rights include, among others, patents obtained from third parties, including rights acquired by Defendants upon Medtronic's acquisition of Kyphon.

115. On information and belief, as part of Defendants' scheme to eliminate competition in the minimally invasive vertebral compression fracture treatment product market and in the alternative kyphoplasty product market, Defendants anticipated and intended that CareFusion and others would become aware of the threatening statements made by Medtronic CEO Bill Hawkins.

116. On February 9, 2010, CareFusion held an earnings conference call. During that conference call, CareFusion's Chairman & Chief Executive Officer, David Schlotterbeck, announced that CareFusion planned to expand its minimally invasive vertebral compression fracture treatment product line by launching a line of balloon kyphoplasty products in April 2010. (Ex. AA, CareFusion Feb. 9, 2010 Earnings Conference Call at 7.)

117. That same day, in light of CareFusion's announcement, David Lewis and Ryan Bachman, analysts for Morgan Stanley who cover the medical device industry including Defendants, contacted CareFusion. (*See* Ex. BB at Feb. 9, 2010 email from Bachman to Borkowski.)

118. On information and belief, the communication from the Morgan Stanley analysts relied on information provided at least in part by Defendants as part of Defendants' scheme to

eliminate CareFusion as a competitor in the minimally invasive vertebral compression fracture treatment product market and in the alternative kyphoplasty product market.

119. After contacting CareFusion, the Morgan Stanley analysts sent an electronic mail message to CareFusion and specifically identified six patents, namely the '888, '404, '043, '734, '110 and '054 patents, that they identified as threats to CareFusion's imminent product launch. (*See id.*)

120. On information and belief, Defendants anticipated and intended that CareFusion and others would become aware of the threatening statements made by Defendants to the analyst community, including the Morgan Stanley analysts, and were made as part of the Defendants' scheme to eliminate CareFusion as a competitor in the minimally invasive vertebral compression fracture treatment product market and in the alternative kyphoplasty product market.

121. Several analyst reports were also published in light of CareFusion's product launch announcement.

122. For example, on February 9, 2010, William Blair & Co. published a report, attached hereto as Exhibit CC, entitled "CareFusion Corporation: Raising Estimates Off Strong Fiscal Second Quarter; See Further Upside."

123. Among other things, that report stated that "[c]oncern related to Medtronic's...intellectual property (acquired with Kyphon) will remain a hot-button issue, but management is focusing on the main patent that expires this month, and suggesting that its product does not infringe the company's other patents. We cannot judge that statement at this point, but would not be surprised if Medtronic came out aggressively against the numerous players targeting this market, so the potential for some litigation expense is relatively high, in our view." (Ex. CC at 3.) On information and belief, Defendants did nothing to discourage or retract these statements.

124. On February 10, 2010, several more analyst reports and news articles were also published in light of CareFusion's product launch announcement.

125. For example, on February 10, 2010, the Dow Jones Newswires published an article, attached hereto as Exhibit DD, entitled "CareFusion to Challenge Medtronic in Spine-Repair Market."

126. On information and belief, the article published by Dow Jones Newswires relied on information provided in pertinent part by Defendants as part of their scheme to eliminate CareFusion as a competitor in the minimally invasive vertebral compression fracture treatment product market and in the alternative kyphoplasty product market.

127. Among other things, the Dow Jones Newswires article stated that "Medtronic…noted in a statement Wednesday that it is the 'only company with a commercially available product in the U.S. for this procedure [balloon kyphoplasty] and the only company with level-one evidence to support the technology." (Ex. DD.) The Dow Jones Newswires article further stated that "the company [Medtronic] said it 'has and will vigorously defend its intellectual property rights in all of our markets, **including Balloon Kyphoplasty**.'" (*Id.* (emphasis added).)

128. On information and belief, Defendants anticipated and intended that CareFusion and others would become aware of the threatening statements made by Defendants to the Dow Jones Newswire and were made as part of the Defendants' scheme to eliminate CareFusion as a competitor in the minimally invasive vertebral compression fracture treatment product market and in the alternative kyphoplasty market.

129. Also on February 10, 2010, J.P. Morgan published an alert, attached hereto as Exhibit EE, entitled "CareFusion Wants In; New Competitor in Kyphoplasty."

130. Among other things, the alert stated that:

- "**On Tuesday's call, CareFusion appeared unfazed by potential hurdles on the IP front.** Recall that Kyphon defended its intellectual property aggressively prior to its acquisition by Medtronic, securing a preliminary injunction against Disc-O-Tech in 2005 that led to the withdrawal of Disc-O-Tech's Sky Bone Expander from the US market."
- "**We expect Medtronic to initiate legal action once CareFusion moves definitely to launch its product domestically.**"

(Ex. EE at 1 (emphasis in original).) On information and belief, Defendants did nothing to discourage or retract these statements.

131. Also on February 10, 2010, Deutsche Bank published an alert, attached hereto as FF, entitled "A shot across Kyphon's bow."

132. Among other things, the alert stated that "[w]e believe that MDT's [Medtronic]'s IP surrounding this technology is strong with multiple patents and, given the importance of this product, would expect a vigorous defend of its IP." (Ex. FF.) On information and belief, Medtronic did nothing to discourage or retract these statements.

133. On February 10, 2010, Deutsch Bank also published a report, attached hereto as Exhibit GG, entitled "CareFusion Corporation: Solid quarter but valuation remains lofty."

134. Among other things, that report stated that "[w]e anticipate a significant patent disagreement with MDT [Medtronic], as CFN [CareFusion] indicated on the call that it believes the main patents have expired, and MDT will likely contend differently." (Ex. GG at 2.) On information and belief, Defendants did nothing to discourage or retract these statements.

135. J.P. Morgan also published a report on February 10, 2010, attached hereto as Exhibit HH, entitled "CareFusion: Solid Sales, Soft Gross Margin in F2Q'10."

136. Among other things, that report stated that "[o]nce CFN [CareFusion] nears official launch, we anticipate legal action from Medtronic, and Kyphon reps will likely use the litigation overhang, along with the lack of published clinical data, as selling points against AVAmax." (Ex. HH at 2.) On information and belief, Defendants did nothing to discourage or retract these statements.

137. On February 15, 2010, the Gray Sheet published an article, attached hereto as Exhibit II, indicating that J.P. Morgan Analyst Michael Weinstein "expects Medtronic to initiate legal action [against CareFusion] closer to U.S. launch [*i.e.*, April 2010]." On information and belief, Defendants did nothing to discourage or retract these statements.

138. On February 23, 2010, Medtronic held another earnings conference call. During that conference call Medtronic's Chairman & CEO, Bill Hawkins, announced that "[f]inally, on Kyphon. Work continues. In regard to a recent announcement of a potential new US competitor, we are very confident in our current family of BKP [balloon kyphoplasty] intellectual property and the protection

it gives our innovative products. We will vigorously defend it against any competitor product that infringes on our technology." (Ex. JJ, Medtronic Feb. 23, 2010 Earnings Conference Call at 4.)

139. On information and belief, the "potential new US competitor" referenced by Medtronic CEO Bill Hawkins was CareFusion.

140. During that same earnings conference call, in response to an analyst's question regarding possible litigation against new competitors in the minimally invasive vertebral compression fracture treatment product market or in the alternative kyphoplasty product market, Medtronic CEO Bill Hawkins reiterated that "we first of all are very confident in the strength of our IP and as I said, we will vigorously defend and assert our IP against any of those that we have reason to believe are infringing our intellectual property. We have a number of patents which protect that space that we really have, if you will, brought to market and developed." (*Id.* at 15.)

141. On information and belief, the "competitors" that the analyst and Medtronic CEO Bill Hawkins were referring to included CareFusion.

142. On information and belief, as part of Defendants' scheme to eliminate CareFusion as a competitor in the minimally invasive vertebral compression fracture treatment product market and in the alternative kyphoplasty product market, Defendants anticipated and intended that CareFusion and others would become aware of the threatening statements made by Medtronic CEO Bill Hawkins.

143. In fact, others did become aware of Medtronic CEO Bill Hawkins threatening statements and interpreted them as a threat of legal action against CareFusion.

144. For example, on February 24, 2010 (the day after Medtronic CEO Bill Hawkins made his public threatening statements), Credit Suisse published, attached hereto as Exhibit KK, a report entitled "Time to Take MDT Out of the Penalty Box."

145. Among other things, the report stated that "[i]n regards to the entrance of CareFusion into the kyphoplasty market, Medtronic is confident in its intellectual property and indicated that it will 'vigorously' defend against any competitor products that infringe on its patents. (CareFusion, expect to be 'served'.)." (Ex. KK at 6.) On information and belief, Defendants did nothing to discourage or retract these statements.

146. Also, on March 1, 2010, the Gray Sheet published an article, attached hereto as Exhibit LL, entitled "Medtronic Spine Sales Down In Fiscal Q3, But Firm Expects A Rebound In 2011," also interpreting Medtronic CEO Bill Hawkins' February 23, 2010 public threatening statements as threat of legal action.

147. Among other things, the Gray Sheet article stated that "Hawkins suggested Medtronic will consider legal action to keep the new device off the market. 'We are very confident in our current family of [balloon kyphoplasty] intellectual property,' he said. 'We will vigorously defend it against any competitor product that infringers our technology." (Ex. LL at 1.)

COUNT I
MONOPOLIZATION UNDER 15 U.S.C. § 2

148. CareFusion incorporates by reference the allegations in paragraphs 1 – 147 above, as if fully alleged herein.

149. Defendants, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, have acquired a monopoly in the minimally invasive vertebral compression fracture treatment product market and in the alternative kyphoplasty product market.

150. Defendants possess monopoly power in the minimally invasive vertebral compression fracture treatment product market and in the alternative kyphoplasty product market. On information and belief, after the acquisition of Kyphon, Defendants obtained and continue to maintain approximately an 85% or more market share in the minimally invasive vertebral compression fracture treatment product market. And, on information and belief, after the acquisition of Kyphon, Defendants obtained and continue to maintain approximately a 97% or more market share in the alternative kyphoplasty product market. The full extent of Defendants' market power will be established after a reasonable opportunity for discovery.

151. Defendants have willfully acquired and maintained their monopoly power in the minimally invasive vertebral compression fracture treatment product market and in the alternative kyphoplasty product market through the anticompetitive, predatory, exclusionary, and/or inequitable conduct outlined above (*see supra* ¶¶ 36 – 147).

152. For example, Defendants' anticompetitive, predatory, exclusionary, and/or inequitable conduct includes but is not limited to: (1) acquiring patents rights in the minimally invasive vertebral

compression fracture treatment product market and in the alternative kyphoplasty market from third parties; (2) acquiring patents from Kyphon, including the '888 and '404 patents, that they knew to be invalid and unenforceable; (3) failing to disclaim or dedicate those invalid and/or unenforceable patents to the public after they acquired them; and (4) using those invalid and/or unenforceable patents and the remainder of their portfolio of patents to keep competitors out of the minimally invasive vertebral compression fracture treatment product market and the alternative kyphoplasty product market.

153. Defendants' anticompetitive, predatory, exclusionary, and/or inequitable conduct also includes, but is not limited to, their history and their predecessor's (Kyphon) history of acquiring third party competitive products in the minimally invasive vertebral compression fracture treatment product market and in the alternative kyphoplasty market without, on information and belief, any intention of actually marketing those competitive products. (*See supra* ¶¶ 46-47, 64-65 and 78-80.) Rather, on information and belief, Defendants acquired these competitive products in order to eliminate competition from the minimally invasive vertebral compression fracture treatment product market and the alternative kyphoplasty product market.

154. Defendants' actions, including acquiring patents from third parties, failing to disclaim or dedicate to the public patents they knew to be invalid and/or unenforceable, and acquiring competitive products that they did not plan to sell in the marketplace, had no legitimate business justification except to destroy competition in the minimally invasive vertebral compression fracture treatment product market and in the alternative kyphoplasty product market.

155. On information and belief, Defendants' anticompetitive, predatory, exclusionary, and/or inequitable conduct (*see supra* at ¶¶ 36 – 147) has had the effect of eliminating and/or diminishing competition in the minimally invasive vertebral compression fracture treatment product market and in the alternative kyphoplasty product market by both (1) eliminating competitors and their competitive products from those markets and (2) preventing competitors from entering those markets.

156. Because market entry conditions are so high (*see supra* ¶¶ 22 – 23), Defendants' monopoly in the minimally invasive vertebral compression fracture treatment product market and the

alternative kyphoplasty product market will continue for years even though the patents covering the basic kyphoplasty procedure, namely the '888 and '404 patents, have expired.

157. On information and belief, Defendants have engaged in this anticompetitive, predatory, exclusionary, and/or inequitable conduct with the intention of maintaining and/or further increasing their monopoly power in the minimally invasive vertebral compression fracture treatment product market and in the alternative kyphoplasty market.

158. Defendants' violation of the Sherman Antitrust Act has harmed CareFusion's ability to compete in the minimally invasive vertebral compression fracture treatment product market and in the alternative kyphoplasty market, for example, by delaying CareFusion's kyphoplasty product(s) for at least two (2) years. This delay in market entry has in turn prevented CareFusion from timely capturing the share of the minimally invasive vertebral compression fracture treatment market and the alternative kyphoplasty product market it would have been able to capture but for Defendants' anticompetitive, predatory, exclusionary, and/or inequitable conduct.

159. Defendants' violation of the Sherman Antitrust Act also threatens to continue to harm CareFusion's ability to compete in the minimally invasive vertebral compression fracture treatment product market and in the alternative kyphoplasty product market, for example, by using illegally acquired third party patent rights to threaten litigation against CareFusion and cast a cloud over its Ava*max*™ balloon kyphoplasty products. (*See, e.g.*, Ex. HH, Feb. 10, 2010 JP Morgan Report at 2 (stating that "Kyphon reps will likely use the litigation overhang....as [a] selling point[] against AVAmax.").)

160. The harm suffered by CareFusion is the direct and intended result of Defendants' anticompetitive, predatory, exclusionary, and/or inequitable conduct.

COUNT II
ATTEMPTED MONOPOLIZATION UNDER 15 U.S.C. § 2

161. CareFusion incorporates by reference the allegations in paragraphs 1 – 160 above, as if fully alleged herein.

162. Defendants, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, has and is attempting to acquire a monopoly in the minimally invasive vertebral compression fracture treatment product market and in the alternative kyphoplasty market.

163. On information and belief, after the acquisition of Kyphon, Defendants obtained and continue to maintain market power in the minimally invasive vertebral compression fracture treatment product market and in the alternative kyphoplasty product market. For example, on information and belief, after the acquisition of Kyphon, Defendants obtained and continue to maintain approximately an 85% or more market share in the minimally invasive vertebral compression fracture treatment product market. And, on information and belief, after the acquisition of Kyphon, Defendants obtained and continue to maintain approximately a 97% or more market share in the alternative kyphoplasty product market. The full extent of Defendants' market power will be established after a reasonable opportunity for discovery.

164. On information and belief, Defendants have acted with the specific intent to acquire a monopoly in the minimally invasive vertebral compression fracture treatment product market and in the alternative kyphoplasty product market through the anticompetitive, predatory, exclusionary, and/or inequitable conduct outlined above (*see supra* ¶¶ 36 – 147).

165. For example, Defendants' anticompetitive, predatory, exclusionary, and/or inequitable conduct includes, but is not limited to: (1) acquiring patent rights from third parties in the minimally invasive vertebral compression fracture treatment product market and in the alternative kyphoplasty product market; (2) acquiring patents, including the '888 and '404 patents, that they knew to be invalid and unenforceable; (3) failing to disclaim or dedicate those invalid and/or unenforceable patents to the public after they acquired them; and (4) using those invalid and/or unenforceable patents and the remainder of their patent portfolio to keep competitors out of the minimally invasive vertebral compression fracture treatment product market and the alternative kyphoplasty product market.

166. Defendants' anticompetitive, predatory, exclusionary, and/or inequitable conduct also includes, but is not limited to, their history and their predecessor's (Kyphon) history of acquiring third party competitive products in the minimally invasive vertebral compression fracture treatment product market and in the alternative kyphoplasty market without, on information and belief, any intention of actually marketing those competitive products. (*See supra* at ¶¶ 46-47, 64-65 and 78-80.) Rather, on information and belief, Defendants acquired these competitive products in order to

State of Delaware and has a principal place of business at 1430 Waukegan Road, McGaw Park, Illinois.

4. On information and belief, Medtronic, Inc. ("Medtronic") is a corporation organized under the laws of the State of Minnesota and has a principal place of business at 710 Medtronic Parkway, Minneapolis, Minnesota.

5. On information and belief, Medtronic Spine LLC ("Medtronic Spine"), a subsidiary of Medtronic, is a corporation organized under the laws of the State of Delaware and has a principal place of business at 1221 Crossman Avenue, Sunnyvale, California.

6. On information and belief, Medtronic Spine is currently doing business as Kyphon Inc. ("Kyphon").

7. On information and belief, Kyphon SARL, a subsidiary of Medtronic, is a Swiss corporation with its principal place of business at Rue de Puits-Godet 12/12A, 2000, Neuchatel, Switzerland.

JURISDICTION AND VENUE

8. This action arises under the antitrust laws of the United States, Title 15 of the United States Code §§ 1 et. seq., and the patent laws of the United States, Title 35 of the United States Code §§ 1 et. seq.

9. This Court has jurisdiction over the subject matter of this action under 15 U.S.C. §§ 4, 15, and 26 and 28 U.S.C. §§ 1331, 1337, 1338(a), 2201, and 2202.

10. On information and belief, this Court has personal jurisdiction, general and specific, over the Defendants because they have sufficient minimum contacts to establish personal jurisdiction in this district. Although it is believed that the extent of Defendants' contacts in this district are extensive, the extent of Defendants' contacts in this district will be established after a reasonable opportunity for discovery.

11. On information and belief, Defendants have systematic and continuous contacts in this judicial district.

12. On information and belief, Defendants regularly transact business within this judicial district.

eliminate competition from the minimally invasive vertebral compression fracture treatment product market and the alternative kyphoplasty product market.

167. Defendants' actions, including acquiring patents from third parties, failing to disclaim or dedicate to the public patents they knew to be invalid and/or unenforceable, and acquiring competitive products that they did not plan to sell in the marketplace, had no legitimate business justification except to destroy competition in the minimally invasive vertebral compression fracture treatment product market and in the alternative kyphoplasty product market.

168. Defendants' anticompetitive, predatory, exclusionary, and/or inequitable conduct, including, but not limited to, the acquisition of patents from third parties, the knowing acquisition of and failure to disclaim or dedicate to the public invalid and unenforceable patent rights, and the acquiring of competitive products that they did not intend to sell in the marketplace gives rise to the dangerous probability that Defendants will succeed in their attempt to acquire a monopoly in the minimally invasive vertebral compression fracture treatment product market and in the alternative kyphoplasty product market.

169. Defendants' violation of the Sherman Antitrust Act has harmed CareFusion's ability to compete in the minimally invasive vertebral compression fracture treatment product market and in the alternative kyphoplasty product market by delaying CareFusion's AVA*max*™ balloon kyphoplasty product for at least two (2) years. This delay in market entry has in turn prevented CareFusion from timely capturing the share of the minimally invasive vertebral compression fracture treatment market and the alternative kyphoplasty product market it would have been able to capture but for Defendants' anticompetitive, predatory, exclusionary, and/or inequitable conduct.

170. Defendants' violation of the Sherman Antitrust Act also threatens to continue to harm CareFusion's ability to compete in the minimally invasive vertebral compression fracture treatment product market and in the alternative kyphoplasty product market, for example, by using illegally acquired third party patent rights to threaten litigation against CareFusion and cast a cloud over its Ava*max*™ balloon kyphoplasty products. (*See, e.g.*, Ex. HH, Feb. 10, 2010 JP Morgan Report at 2 (stating that "Kyphon reps will likely use the litigation overhang....as [a] selling point[] against AVAmax.").)

171. The harm suffered by CareFusion is the direct and intended result of Defendants' anticompetitive, predatory, exclusionary, and/or inequitable conduct.

COUNT III
DECLARATORY JUDGMENT OF NONINFRINGEMENT AND INVALIDITY OF U.S. PATENT NO. 6,235,043

172. CareFusion incorporates by reference the allegations of paragraphs 1 – 168 above, as if fully alleged herein.

173. Kyphon SARL, which on information and belief is a subsidiary of Medtronic, is the current recorded assignee of the '043 patent.

174. Since CareFusion's announcement of its AVA*max*™ balloon kyphoplasty product launch, the analyst community has repeatedly stated that a lawsuit from Defendants was forthcoming. (*See generally supra* ¶¶ 117 – 147.)

175. For example, on February 9, 2010, just hours after CareFusion announced the imminent launch of AVA*max*™ balloon kyphoplasty product, Morgan Stanley analysts sent an electronic message to CareFusion identifying the '043 patent as a threat to CareFusion's imminent product launch. (*See* Ex. BB, Bachman email to Borkowski.)

176. On information and belief, the Morgan Stanley analysts have covered the medical device industry for years, have and continue to work closely with Defendants, and received information regarding the '043 patent from Defendants.

177. Since CareFusion's announcement of its AVA*max*™ balloon kyphoplasty product launch, Defendants have also directly and publicly stated that it will "vigorously defend and assert our IP" related to balloon kyphoplasty. (Ex. JJ, Medtronic Feb. 23, 2010 Earnings Conference Call at 15; *see also id.* at 4.)

178. Defendants' actions, combined with the totality of the circumstances, including but not limited to Defendants' litigation history, have therefore created a substantial controversy between Defendants and CareFusion regarding the alleged infringement of the '043 patent by CareFusion's AVA*max*™ balloon kyphoplasty products.[1]

[1] *See, e.g., Alien Tech. Corp. v. Intermec, Inc.*, No. 06-51, 2007 U.S. Dist. LEXIS 2851, at *3-5, 10-12 (D.N.D. Jan. 4, 2007) (finding an actual case or controversy existed in light of threatening (continued)

179. On information and belief, one or more claims of the '043 patent are invalid for failure to meet the requirements for patentability, including the requirements of 35 U.S.C. §§ 102, 103, and 112.

180. CareFusion's AVA*max*™ balloon kyphoplasty products do not infringe any valid claim of the '043 patent.

181. An actual and justiciable controversy exists between Defendants and CareFusion regarding invalidity and non-infringement of the '043 patent.

COUNT IV
DECLARATORY JUDGMENT OF NONINFRINGEMENT AND INVALIDITY OF U.S. PATENT NO. 6,241,734

182. CareFusion incorporates by reference the allegations of paragraphs 1 – 181 above, as if fully alleged herein.

183. Kyphon SARL, which on information and belief is a subsidiary of Medtronic, is the current recorded assignee of the '734 patent.

184. Since CareFusion's announcement of its AVA*max*™ balloon kyphoplasty product launch, the analyst community has repeatedly stated that a lawsuit from Defendants was forthcoming. (*See generally supra* ¶¶ 117 – 147.)

185. For example, on February 9, 2010, just hours after CareFusion announced the imminent launch of AVA*max*™ balloon kyphoplasty product, Morgan Stanley analysts sent an electronic message to CareFusion identifying the '734 patent as a threat to CareFusion's imminent product launch. (*See* Ex. BB, Bachman email to Borkowski.)

186. On information and belief, the Morgan Stanley analysts have covered the medical device industry for years, have and continue to work closely with Defendants, and received information regarding the '734 patent from Defendants.

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statements made during an earnings conference call and defendants' prior litigation regarding the patents at issue); *Dr. Reddy's Labs., LTD v. AaiPharma, Inc.*, No. 01-10102, 2002 U.S. Dist. LEXIS 17287, at *8-24 (S.D.N.Y. Sept. 19, 2002) (holding that threatening statements made to entire industry in two separate Wall Street Journal articles sufficient to establish declaratory judgment jurisdiction).

187. Since CareFusion's announcement of its AVA*max*™ balloon kyphoplasty product launch, Defendants have also directly and publicly stated that it will "vigorously defend and assert our IP" related to balloon kyphoplasty. (Ex. JJ, Feb. 23, 2010 Medtronic Earnings Conference Call at 15; *see also id.* at 4.)

188. Defendants' actions, combined with the totality of the circumstances, including but not limited to Defendants' litigation history, have therefore created a substantial controversy between Defendants and CareFusion regarding the alleged infringement of the '734 patent by CareFusion's AVA*max*™ balloon kyphoplasty products. (*See supra* ¶ 178 n.1.)

189. On information and belief, one or more claims of the '734 patent are invalid for failure to meet the requirements for patentability, including the requirements of 35 U.S.C. §§ 102, 103, and 112.

190. CareFusion's AVA*max*™ balloon kyphoplasty products do not infringe any valid claim of the '734 patent.

191. An actual and justiciable controversy exists between Defendants and CareFusion regarding invalidity and non-infringement of the '734 patent.

COUNT V
DECLARATORY JUDGMENT OF NONINFRINGEMENT AND INVALIDITY OF U.S. PATENT NO. 6,248,110

192. CareFusion incorporates by reference the allegations of paragraphs 1 – 191 above, as if fully alleged herein.

193. Medtronic Spine is the current recorded assignee of the '110 patent.

194. Since CareFusion's announcement of its AVA*max*™ balloon kyphoplasty product launch, the analyst community has repeatedly stated that a lawsuit from Defendants was forthcoming. (*See supra* ¶¶ 117 – 147.)

195. For example, on February 9, 2010, just hours after CareFusion announced the imminent launch of AVA*max*™ balloon kyphoplasty product, Morgan Stanley analysts sent an electronic message to CareFusion identifying the '110 patent as a threat to CareFusion's imminent product launch. (*See* Ex. BB, Bachman email to Borkowski.)

196. On information and belief, the Morgan Stanley analysts have covered the medical device industry for years, have and continue to work closely with Defendants, and received information regarding the '110 patent from Defendants.

197. Since CareFusion's announcement of its AVA*max*™ balloon kyphoplasty product launch, Defendants have also directly and publicly stated that it will "vigorously defend and assert our IP" related to balloon kyphoplasty. (Ex. JJ, Feb. 23, 2010 Medtronic Earnings Conference Call at 15; *see also id.* at 4.)

198. Defendants' actions, combined with the totality of the circumstances, including but not limited to Defendants' litigation history, have therefore created a substantial controversy between Defendants and CareFusion regarding the alleged infringement of the '110 patent by CareFusion's AVA*max*™ balloon kyphoplasty products. (*See supra* ¶ 178 n.1.)

199. On information and belief, one or more claims of the '110 patent are invalid for failure to meet the requirements for patentability, including the requirements of 35 U.S.C. §§ 102, 103, and 112.

200. CareFusion's AVA*max*™ balloon kyphoplasty products do not infringe any valid claim of the '110 patent.

201. An actual and justiciable controversy exists between Defendants and CareFusion regarding invalidity and non-infringement of the '110 patent.

COUNT VI
DECLARATORY JUDGMENT OF NONINFRINGEMENT AND INVALIDITY OF U.S. PATENT NO. 6,613,054

202. CareFusion incorporates by reference the allegations of paragraphs 1 – 201 above, as if fully alleged herein.

203. Kyphon SARL, which on information and belief is a subsidiary of Medtronic, is the current recorded assignee of the '054 patent.

204. Since CareFusion's announcement of its AVA*max*™ balloon kyphoplasty product launch, the analyst community has repeatedly stated that a lawsuit from Defendants was forthcoming. (*See supra* ¶¶ 117 – 147.)

205. For example, on February 9, 2010, just hours after CareFusion announced the imminent launch of AVA*max*™ balloon kyphoplasty product, Morgan Stanley analysts sent an electronic message to CareFusion identifying the '054 patent as a threat to CareFusion's imminent product launch. (*See* Ex. BB, Bachman email to Borkowski.)

206. On information and belief, the Morgan Stanley analysts have covered the medical device industry for years, have and continue to work closely with Defendants, and received information regarding the '054 patent from Defendants.

207. Since CareFusion's announcement of its AVA*max*™ balloon kyphoplasty product launch, Defendants have also directly and publicly stated that it will "vigorously defend and assert our IP" related to balloon kyphoplasty. (Ex. JJ, Feb. 23, 2010 Medtronic Earnings Conference Call at 15; *see also id.* at 4.)

208. Defendants' actions, combined with the totality of the circumstances, including but not limited to Defendants' litigation history, have therefore created a substantial controversy between Defendants and CareFusion regarding the alleged infringement of the '054 patent by CareFusion's AVA*max*™ balloon kyphoplasty products. (*See supra* ¶ 178 n.1.)

209. On information and belief, one or more claims of the '054 patent are invalid for failure to meet the requirements for patentability, including the requirements of 35 U.S.C. §§ 102, 103, and 112.

210. CareFusion's AVA*max*™ balloon kyphoplasty products do not infringe any valid claim of the '054 patent.

211. An actual and justiciable controversy exists between Defendants and CareFusion regarding invalidity and non-infringement of the '054 patent.

PRAYER FOR RELIEF

WHEREFORE, CareFusion respectfully requests entry of judgment in its favor and the following relief, including:

A. That Defendants account for damages sustained by CareFusion as a result of Defendants' violations of the antitrust laws;

B. That the damages resulting from Defendants' violations of the antitrust laws be trebled as required by 15 U.S.C. § 15(a);

C. That Defendants, and all related entities, be permanently enjoined from threatening CareFusion with patents it knows to be either invalid or unenforceable;

D. That Defendants, and all related entities, be ordered to immediately disclaim and dedicate to the public each and every patent they own, or have exclusive rights in, that relates in whole or in part to minimally invasive vertebral compression fracture treatment products, to the public and to so inform the United States Patent and Trademark Office;

E. That Defendants, and all related entities, be enjoined from enforcing each and every patent they own, or have exclusive rights in, that relates in whole or in part to minimally invasive vertebral compression fracture treatment products, for a minimum of ten (10) years from the date of the Order;

F. That all potential or actual competitors of Defendants in the minimally invasive vertebral compression fracture treatment product market be given a zero sum paid up license under each and every patent now owned or controlled by Defendants that relates to said market;

G. That CareFusion be awarded its costs and reasonable attorney fees associated with its antitrust counts as required by 15 U.S.C. § 15(a);

H. That CareFusion be awarded prejudgment interest on any award made pursuant to 15 U.S.C. § 15(a);

I. That one or more claims of the '043 patent be declared invalid;

J. That one or more claims of the '734 patent be declared invalid;

K. That one or more claims of the '110 patent be declared invalid;

L. That one or more claims of the '054 patent be declared invalid;

M. That CareFusion be declared to not be liable for any infringement, contributory infringement, or for inducing the infringement of any valid claim of the '043 patent;

N. That CareFusion be declared to not be liable for any infringement, contributory infringement, or for inducing the infringement of any valid claim of the '734 patent;

O. That CareFusion be declared to not be liable for any infringement, contributory infringement, or for inducing the infringement of any valid claim of the '110 patent;

P. That CareFusion be declared to not be liable for any infringement, contributory infringement, or for inducing the infringement of any valid claim of the '054 patent;

Q. That this case be declared "exceptional" and that CareFusion be awarded its expenses, costs, and attorneys' fees pursuant to 35 U.S.C. § 285;

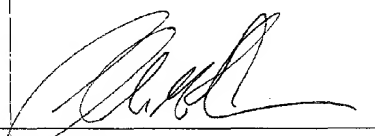
R. That CareFusion be awarded its costs, attorneys' fees, and expenses incurred in this action pursuant to applicable state and federal laws; and

S. That the Court grant CareFusion such other and further relief as the Court may deem just and proper.

JURY DEMAND

CareFusion demands a trial by jury on all issues so triable.

Respectfully submitted,



Dated: March 15, 2010

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13. On information and belief, Defendants regularly sell products in this judicial district. Defendants derive substantial revenues from sales in this district.

14. Venue is proper in this district under 15 U.S.C. §§ 15(a), 22, and 26 and 28 U.S.C. §§ 1391(b) and (c).

INTRADISTRICT ASSIGNMENT

15. Pursuant to Civil L.R. 3-2(c), this action may be assigned on a district-wide basis.

TRADE AND COMMERCE

16. Defendants are engaged in activity affecting interstate commerce including substantial sales of minimally invasive vertebral compression fracture treatment products in the United States.

17. Defendants' predatory actions that give rise to the antitrust claims asserted herein have an intended and substantial effect within the United States, including harming CareFusion's ability to compete in interstate commerce related to minimally invasive vertebral compression fracture treatment products.

THE RELEVANT PRODUCT MARKETS

18. A relevant product market is the minimally invasive vertebral compression fracture treatment product market, which includes, but is not limited to, kyphoplasty (by balloon or otherwise) and vertebroplasty.

19. Alternatively, a relevant product market is the kyphoplasty product market.

20. The relevant geographic market is the United States.

21. The relevant time period is 1998 to the present.

22. Entry into the minimally invasive vertebral compression fracture treatment product market and the alternative kyphoplasty product market is extremely difficult, expensive, and time-consuming because of, among other things, extensive regulatory approval time, the high cost of developing and producing a minimally invasive vertebral compression fracture treatment product, physician unwillingness to switch product manufacturers, physician preferences toward devices with long clinical track records, and Kyphon's/Medtronic's perceived market leadership in the minimally invasive vertebral compression fracture treatment product market and in the alternative kyphoplasty product market.

23. Because of Defendants' (including Defendants' predecessor) aggressive enforcement and threatened enforcement of the extensive portfolio of patents they allegedly own/owned, including enforcement or threatened enforcement of United States Patent No. 4,969,888 ("the '888 patent"; attached hereto as Exhibit E) and United States Patent No. 5,108,404 ("the '404 patent"; attached hereto as Exhibit F), both of which relate to the basic kyphoplasty procedure, prior to the February 2009 expiration of the '888 and '404 patents, Defendants' patents also constituted a significant barrier to the entry into the minimally invasive vertebral compression fracture treatment product market and the alternative kyphoplasty product market.

FACTUAL BACKGROUND

24. Vertebroplasty is a minimally invasive vertebral compression fracture treatment procedure. Specifically, it is a surgical procedure developed at least in France in 1984 for the treatment of vertebral compression fractures, which are commonly caused by osteoporosis. Vertebroplasty involves supplying bone cement, bone paste or related flowable material into the affected vertebral body or bodies. The bone cement, bone paste, or related flowable material hardens after it has been supplied to the vertebral body or bodies.

25. Kyphoplasty is another type of minimally invasive vertebral compression fracture treatment procedure. Kyphoplasty is a surgical procedure that, according to Kyphon, was developed in the late 1980s and early 1990s by Dr. Mark Reiley ("Reiley") and Arie Scholten ("Scholten"). Kyphoplasty is identical to vertebroplasty except for the addition of one step. In kyphoplasty, before supplying bone cement, bone paste, or related flowable material to the affected vertebral body or bodies, a void is created in the affected vertebral body or bodies. The void is most commonly created by the insertion and inflation of a balloon within the affected vertebral body or bodies, but can be created by other devices such as cutting tools or non-balloon expandable devices. Bone cement, bone paste, or related flowable material is then injected into the void created by, for example, a balloon. The bone cement, bone paste, or related flowable material hardens after it has been supplied to the vertebral body or bodies.

26. On information and belief, Reiley and Scholten developed the kyphoplasty procedure by copying balloon catheters used in coronary angioplasty procedures and by building upon the

vertebroplasty procedures developed before kyphoplasty. (Ex. G, David Cassak, "Kyphon: A Trial Balloon Succeeds In Spine," *In Vivo*, July 1, 2002, at 4; Ex. H, "Tapping Into New Treatment Firm Aims To Sell Heart Equipment For Spinal Use," Chicago Tribune, Sept. 25, 1999, at Business p. 1; Ex. I, Medtronic Amended Answer to Amended Complaint, Civ. Action No. 05-2863 (W.D. Tenn.) at ¶¶ 67-77.)

27. Reiley and Scholten filed their initial patent application relating to kyphoplasty on February 9, 1989. That application, entitled "Surgical Protocol For Fixation Of Osteoporotic Bone Using Inflatable Device," ultimately issued on November 13, 1990 as the '888 patent. (Ex. E at Cover.)

28. On August 15, 1990, Reiley and Scholten filed a continuation-in-part patent application to the patent application that issued as the '888 patent. This continuation-in-part patent application, entitled "Surgical Protocol For Fixation Of Bone Using Inflatable Device," issued on April 28, 1992 as the '404 patent. (Ex. F at Cover.)

29. According to Kyphon, the '888 and '404 patents contain broad claims covering the basic kyphoplasty procedure, including kyphoplasty performed with a balloon and kyphoplasty performed with non-balloon instruments to create a void or voids in vertebral bodies.

30. In 1994, Kyphon was founded by, among others, Reiley and Scholten.

31. On August 7, 1996, Reiley and Scholten assigned the '888 and '404 patents to Kyphon.

32. The '888 and '404 patents expired on February 9, 2009.

33. Since the filing of the patent applications leading to the '888 and '404 patents, Kyphon has continued to seek and obtain numerous patents for minor, trivial, and/or obvious modifications to its kyphoplasty procedures and/or the equipment used during a kyphoplasty procedure.

34. On information and belief, Kyphon obtained approximately fifty (50) or more patents directed to kyphoplasty procedures and equipment.

35. On May 1, 2006, in furtherance of Defendants' scheme to eliminate competition in the minimally invasive vertebral compression fracture treatment product market or in the alternative kyphoplasty product market, Kyphon issued a press release asserting that at least one of these

additional patents "extends our patent coverage for key aspects of the fundamental method of performing kyphoplasty" and "significantly bolsters our exiting portfolio and reflects both our continuing commitment to technological innovation and our constant efforts to aggressively pursue patent protection in our core markets in both the U.S. and abroad." (Ex. J, Kyphon May 1, 2006 Press Release at 1.)

Kyphon's Anticompetitive Acquisition Of Patent Rights Related To Minimally Invasive Vertebral Compression Fracture Treatment Products

36. On information and belief, since Kyphon's founding, Defendants have actively sought to acquire additional patents related to the minimally invasive vertebral compression fracture treatment products, including kyphoplasty, from third parties as part of a scheme to eliminate and/or reduce competition in that market and in the alternative kyphoplasty product market.

37. For example, in August 2002, Kyphon paid approximately at least $12.25 million for an exclusive license to approximately at least 23 patents naming Dr. Peter M. Bonutti as the inventor.

38. On information and belief, the licensed Dr. Bonutti patents included at least: 5,163,949; 5,197,971; 5,295,994; 5,331,975; 5,345,927; 5,514,153; 5,667,520; 5,601,590; 5,685,826; 5,707,390; 5,716,325; 5,827,318; 5,860,997; 5,888,196; 5,954,739; 6,017,305; 6,042,596; 6,102,928; 6,171,236; 6,171,299; 6,187,023; 6,277,136; and 6,358,266.

39. On information and belief, Kyphon's acquisition of rights in the Dr. Bonutti patents was part of Defendants' scheme to eliminate competition in the minimally invasive vertebral compression fracture treatment product market and in the alternative kyphoplasty product market, and had the effect of eliminating and/or diminishing competition in those markets.

40. In February 2003, Kyphon acquired the German company Sanatis GmbH for approximately at least $3.2 million.

41. This acquisition included the transfer of at least four pending patent applications to Kyphon. At least one those patents subsequently issued, namely United States Patent No. 6,692,563.

42. On information and belief, Kyphon's acquisition of Sanatis, including Sanatis' patent rights, was part of Defendants' scheme to eliminate competition in the minimally invasive vertebral compression fracture treatment product market and in the alternative kyphoplasty product market,

and had the effect of eliminating and/or diminishing competition in those markets by eliminating a competitor from those markets.

43. In April 2005, Kyphon paid approximately at least $1 million for an exclusive license to patents owned by Dr. J. Lee Berger.

44. On information and belief, these patents included at least: 5,423,850; 5,480,400; 5,545,136; 5,658,310; and 6,706,069.

45. On information and belief, Kyphon's acquisition of these patent rights from Dr. Berger was part of Defendants' scheme to eliminate competition in the minimally invasive vertebral compression fracture treatment product market and in the alternative kyphoplasty product market, and had the effect of eliminating and/or diminishing competition in those markets.

46. In November 2005, Kyphon obtained an exclusive license to technology developed by Dr. Harvinder S. Sandhu.

47. On information and belief, Kyphon's acquisition of these intellectual property rights from Dr. Sandhu was part of Defendants' scheme to eliminate competition in the minimally invasive vertebral compression fracture treatment product market and in the alternative kyphoplasty product market, and had the effect of eliminating and/or diminishing competition in those markets by preventing a competitive product from entering those markets.

48. The full extent of the Defendants' scheme and illegal activities in furtherance of their scheme for eliminating competition in the minimally invasive vertebral compression fracture treatment product market and in the alternative kyphoplasty product market will be established after a reasonable opportunity for discovery.

Defendants' Anticompetitive Pricing Scheme

49. On information and belief, since Kyphon's founding, Defendants have sought to use their monopoly power to artificially raise the prices on their kyphoplasty products.

50. For example, in or about 2000, Kyphon embarked on a years-long pricing and marketing scheme that defrauded Medicare and enabled it to charge higher, inflated prices for its kyphoplasty products. (*See* Ex. K, Department of Justice May 22, 2008 Press Release.)

51. On information and belief, to entice certain hospitals and doctors to pay these higher, inflated prices for its kyphoplasty products, Kyphon convinced those hospitals and doctors to keep patients receiving the kyphoplasty procedure overnight, even though kyphoplasty is typically an outpatient procedure, so that Medicare could be billed at a higher rate for an inpatient procedure.

52. On information and belief, Kyphon's pricing and marketing scheme, which was facilitated by its monopoly power, defrauded the United States government of millions of dollars.

53. As a result of Kyphon's illegal pricing and marketing schemes, Kyphon settled with the United States Department of Justice for $75 million. The fine was ultimately paid by Medtronic Spine, Kyphon's corporate successor. (*See id.*)

54. On information and belief, in addition to the illegal pricing and marketing schemes used to defraud Medicare, since settling for $75 million with the Federal Trade Commission, Defendants have continued to use their dominant market position to charge artificially high prices as part of Defendants' anticompetitive and illegal scheme to eliminate competition in the minimally invasive vertebral compression fracture treatment product market and in the alternative kyphoplasty product market.

Kyphon's Enforcement Of Their Invalid And Unenforceable Patent Rights

55. Since its founding, to keep its dominant position in the minimally invasive vertebral compression fracture treatment product market and in the alternative kyphoplasty product market, Kyphon actively sought to prevent competitors from entering those markets by repeatedly enforcing and threatening enforcement of its patent rights against those competitors.

56. For example, on April 2, 2004, Kyphon filed a lawsuit against Disc-O-Tech Medical Technologies, Ltd. and Disc Orthopaedic Technologies Inc. (collectively "Disc-O-Tech") alleging infringement of the '888, '404, '043, and '110 patents. (*See Kyphon Inc. v. Disc-O-Tech Med. Techs., Ltd., et al.*, Civil Action No. 04-204-JJF (D. Del.).)

57. Just days later, on April 5, 2004, Kyphon also filed a complaint against Disc-O-Tech with the International Trade Commission alleging infringement of those same patents. (*See In re Certain Med. Devices Used to Compact Inner Bone Tissue and Prods. Containing Same*, Investigation No. 377-TA-507.)